

Remarks

In the specification, paragraphs on pages 6, 14, and 15 were amended to remove references to hyperlinks, and paragraph on page 12 was amended to correct minor editorial problems.

Claims 51-53, 55, 60, 63, 64, and 66-82 were pending in the present application. Claims 55, 60, 63, and 66 were cancelled. Claim 83 was added. Claims 51, 52, 64, and 82 were amended. Therefore, claims 51-53, 64, and 67-83 are now pending.

Support for the new and amended claims can be found throughout the specification, for example:

Claim 51: page 36, lines 3-5 and 18-21.

Claim 52: page 2, line 23.

Claims 51 and 64: amended to remove reference to SEQ ID NO: 1 due to the restriction requirement.

Claim 82: page 18, line 21 - page 19, line 9.

Claim 83: Claims 51 and 64.

Applicants thank Examiner Rawlings for the courtesy of a telephone interview with Applicants' representative Sheree Lynn Rybak, Ph.D. on August 29, 2003. During this interview the rejections and proposed amendments were discussed. Applicants' representative explained that claim 51 would be amended to clarify that the method is directed to determining if a subject has cancer. It was agreed that this amendment would overcome the 35 U.S.C. § 112 first and second paragraph rejections of claim 51 as long as Applicants could demonstrate where in the specification support for such an amendment could be found.

In addition, Applicants' representative explained that the 70% sequence identity language in claim 51 would be amended to 95% sequence identity. Examiner Rawlings indicated that the 35 U.S.C. § 112 first paragraph rejection based on the 70% sequence identity language might be overcome if Applicants clarified that their intention is to cover allelic variations of a 15 kDa selenoprotein, and not other non-15 kDa selenoproteins whose expression is not decreased in cancer cells.

Specification

As requested by the Examiner, the specification has been amended to remove references to hyperlinks and properly designate trademarks.

In view of these amendments, Applicants request that the objection to the specification be withdrawn.

Restriction Requirement and Claim Objections

Applicants thank Examiner Rawlings for recombining several of the claim groups.

In view of the Restriction Requirement, claims 51 and 64 have been amended to remove references to a non-elected invention (SEQ ID NO: 1). Therefore, Applicants request that the objection to the claims be withdrawn.

35 U.S.C. § 112, first paragraph

Claims 52, 60, 66, 70, 77 and 82 were rejected under 35 U.S.C. § 112, first paragraph on the ground that these claims contain subject matter that was not described in the specification.

Claim 52 was amended to include the exact language found on page 2, line 23 of the specification.

Claim 66 was cancelled.

Claims 60 and 82 were rejected on the ground that there was not sufficient support in the specification for these claims. Although Applicants respectfully disagree, in order to expedite prosecution, claim 60 was cancelled and claim 82 was amended to remove the thyroid cell language.

Claim 70 was rejected on the ground that there was not sufficient antecedent basis in the specification for recitation "any 15 kDa selenoprotein" in the claim. Applicants respectfully disagree and request reconsideration. Specific support for the language "any 15 kDa selenoprotein" can be found in claim 9 as filed with the original application. Therefore, this

language is not new matter as it was present in the application as filed. In addition, the specification discloses a genus of 15 kDa selenoproteins. As noted on page 5, line 38-page 6, line 2, the term “15 kDa selenoprotein” refers generically to mammalian selenoproteins. In addition, the application discloses mouse and human 15 kDa selenoproteins, as well as variants thereof (for example see page 6 lines 5-7; page 6, line 28-page 7, line 13; page 15, line 21- page 16 17; page 24 lines 11-21; and Figure 2).

Claim 77 was rejected on the ground that there was not sufficient antecedent basis in the specification for recitation “wherein the antibody is bound to a solid substrate” in the claim. Applicants respectfully disagree and request reconsideration. Specific support for the language “an antibody bound to a solid substrate” can be found on page 36, lines 25-26.

Claims 51-53, 55, 60, 63, 64 66-77 and 80-82 were rejected on the ground that the specification only provides an adequate description of SEQ ID NO: 1, and not for sequences having at least 70% identity to SEQ ID NO: 1. Applicants respectfully disagree and request reconsideration. The specification clearly describes how one skilled in the art can make substitutions in SEQ ID NOS: 1 or 4, for example by using the conservative substitutions shown in Table 4 on page 24. Based on this Table, those skilled in the art could instantly envision several members of the genus of polypeptides to which the claims refer. Applicants have provided further guidance as to which amino acids are important for function, by cloning the corresponding mouse sequence (SEQ ID NO: 9) and showing an alignment of a human and mouse 15 kDa selenoprotein, as well as a *C. elegans* and rice homolog (Figure 2). Figure 2 demonstrates which amino acids are conserved between various species of 15 kDa selenoprotein, and which are not. Those skilled in the art understand that regions of higher homology are more important to preserve function than are regions having less homology. Based on the information provided in the application, Applicants have provided guidance as to which amino acids are important for function, and therefore, which can be substituted without substantial loss of function of a 15 kDa selenoprotein. Therefore, the specification satisfies the enablement and written description requirements for variant 15 kDa selenoprotein sequences.

In order to expedite prosecution, Applicant has amended claim 51 to refer to a 15 kDa selenoprotein comprising at least 95% sequence identity to SEQ ID NO: 4, in order to clarify that

Applicant is not trying to include other non-15 kDa selenoproteins within the scope of the claim, but rather wants to ensure that natural allelic variations that occur between individual members in a population are within the scope of the claim.

Claims 51-53, 55, 60, 63, 64 66-77 and 80-82 were rejected on the ground that the subject matter of the claims is not enabled for assessing a subject's risk for developing cancer. Although Applicants respectfully disagree, in order to expedite prosecution, claim 51 has been amended to clarify that the claim is directed to determining if the subject currently has cancer. The specification provides enablement for determining if a subject suffers from cancer, because *in vivo* data using samples obtained from a live organism or from tissue culture cells demonstrated that expression of a 15 kDa selenoprotein was decreased in cancer cells relative to normal control cells (see page 18, line 14- page 19, line 9 of the specification). Therefore, the inventors have satisfied the enablement requirement by demonstrating that the claimed method can be used to determine if a subject has cancer. In view of the data provided in the specification, the skilled artisan would have a reasonable expectation of successfully using the claimed invention to assess whether a subject had a cancer related to decreased expression of a 15 kDa selenoprotein.

In view of these amendments and evidence of support in the specification, Applicants request that the 35 U.S.C. § 112, first paragraph rejection be withdrawn.

35 U.S.C. § 112, second paragraph

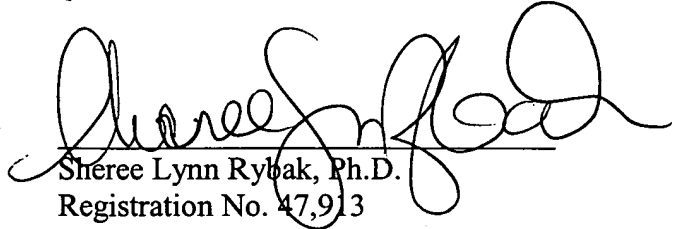
Claims 51-53, 55, 60, 63, 64 66-77 and 80-82 were rejected under 35 U.S.C. § 112, second paragraph on the ground that the claims are indefinite. Applicants have amended the phrase "an increased risk of developing cancer" in claim 51 to "having cancer" to clarify the language of the claims. In view of this amendment, Applicants request that the 35 U.S.C. § 112, second paragraph rejection be withdrawn.

If any matters remain before a notice of allowance is issued, the examiner is invited to telephone the undersigned.

Respectfully submitted,

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